

DETAILED ACTION

Applicant's response filed August 25, 2011 is acknowledged. Claim 1 is amended and claims 24-25 are newly added. Claims 1-6, 10-12, and 15-25 are further considered on the merits.

Response to Amendment

In response to the amendment, the examiner maintains the grounds of rejection set forth in the office action dated March 25, 2011.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. **Claims 1-6 and 17-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., JP 2003-149096 (Tanaka, IDS) in view of Meyering et al., US 6280791 (Meyering).
3. Regarding claims 1-2 and 4-5, Tanaka discloses a composite porous membrane comprising an organic polymer coating and at least one supporting porous membrane (¶ 0009-0010, 0019, 0030) wherein the porous membrane has an opening ratio between 10% and 90% (fig. 4), an average pore diameter of 7 to 14 μm (¶ 0019, 0030) with a standard deviation in pore diameter between 0 and 0.6 and percentage of through-pores to all the pores of the porous membrane is 30% or more (implicit in fig. 2-4). Furthermore, it can be envisaged that the pore diameter of the supporting porous membrane be at least 50% of the porous membrane, since Tanaka discloses multi-

layered membranes comprising an upper membrane with pore diameters of 5.5-8.5 μm and a lower membrane with a pore diameter of 3.5 μm (§ 0019).

4. Tanaka does not explicitly disclose the thickness of the porous membrane. However, Meyering discloses composite membranes for microfiltration techniques (abstract) wherein separate layers have a thickness of about 25 μm (C4/L4-17).

5. Therefore, at the time of invention, it would have been obvious to one having ordinary skill in the art to modify the membrane of Tanaka to comprise a membrane having thicknesses taught by Meyering since it has been shown that reducing the thickness of a membrane to less than 50 μm increases the overall flow rate and reduces the pressure drop across the membrane, thereby increasing performance of the filtration membrane (Meyering, C2/L57-59).

6. Lastly, Tanaka (in view of Meyering) does not explicitly disclose the composite membrane having a density from 0.1 to 0.5 g/cm^3 . However, Tanaka discloses a series of membranes wherein the volume of solution added during the manufacture of said membrane is varied from 5ml to 10ml to 20ml (§ 0028) or the concentration of said solution is varied from 1 g/l to 20 g/l (§ 0029). Tanaka discloses that by increasing the volume or concentration of the membrane forming mixture, the pore size of the final composite membrane is increased while the overall membrane density is decreased (§ 0028, Fig. 2). Tanaka recognizes that density is a result effective variable, dependent upon variations in solution volume and/or concentration during membrane manufacture.

7. Therefore, at the time of invention, it would have been obvious to one having ordinary skill in the art to modify the membrane of Tanaka (in view of Meyering) to have

the recited density, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (MPEP 2144.05, Section II, Part B).

8. Regarding claims 3 and 21-22, Tanaka (in view of Meyering) does not disclose that the average membrane thickness of the porous membrane is between .1 and 20 μm . However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have such a membrane thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (MPEP 2144.05, Section II, Part A). Additionally, Tanaka (in view of Meyering) discloses a composite membrane wherein the supporting porous membrane has an average pore diameter between 1 and 100 μm (§ 0019).

9. Regarding claim 6, Tanaka (in view of Meyering) discloses a composite porous membrane, where it is inherent that the porous membrane can be used to culture cell solutions, absent evidence to the contrary. As it has been held that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)*.

10. Claim(s) 17-20 recite limitations regarding manipulative steps to bring about a specific product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in

the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113).

11. Regarding claim 23, Tanaka (in view of Meyering) discloses a porous membrane wherein the porous membrane has an opening ration between 15% and 80% (implicit in fig. 1-4).

12. Regarding claims 24-25, Tanaka does not explicitly disclose a membrane wherein the porous support comprises fibers. However, Meyering discloses multiple layer reinforced filtration membranes (abstract), wherein a porous support layer comprises fibers having a fiber diameter between 0.1 and 50 microns (C5/L51-C6/L7).

13. At the time of invention, it would have been obvious to one having ordinary skill in the art to cast one of the membranes of Tanaka onto the fibrous support disclosed in Meyering in order to provide structural rigidity to the separation membrane and to increase the durability of said separation membrane without increasing the pressure drop across a composite membrane (Meyering, C5/L56-C6/L4).

14. **Claims 10-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka in view of Meyering as applied to claims 1-6, and in further view of Sheik-Ali, US 6645388 (Sheik-Ali).

15. As to Claims 10 and 12, Tanaka (in view of Meyering) discloses a leukocyte removal filter device comprising a plurality of filter elements (§ 0019) and the composite membrane for use in the leukocyte depletion medium as shown in the 103(a) rejection of Claim 1.

16. Tanaka (in view of Meyering) does not appear to expressly disclose a prefilter (first filter) at the entrance of the suspension. However, Sheik-Ali discloses a prefilter in leukocyte depletion device at the entrance capable of removing leukocytes (C7/L27-30) prior to the other filtration elements at the exit side.

17. At the time of the invention it would have been obvious to a person having ordinary skill in the art to include the prefilter of Sheik-Ali in the leukocyte removal device of Tanaka (in view of Meyering). The motivation would have been to remove gel particulates from the hemocyte suspension to improve filtration efficiency.

18. Furthermore, It would have been obvious to a person having ordinary skill in the art that the composite membranes of Tanaka (in view of Meyering) have a higher effective filtration area (based an increased porosity and uniform pore size) and therefore requires a lesser volume of filter material to obtain the desired degree of leukocyte removal. It is desirable to have a lower filter volume as it reduces the amount of fluid retained in filter medium. Therefore, it would have been obvious to optimize the volume of the filter element to have a volume between 2 and 18 cm³ as it has been held obvious to optimize a result effective variable. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

19. As to Claim 11, Sheik-Ali discloses that in order to achieve the desired leukocyte depletion it is necessary to have an effective area of the filter between 4 and 300 cm² (C7/L36-37).

20. **Claims 15-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mussi et al., US 5665596 (Mussi) in view of Tanaka and Meyering as relied upon in the rejection of claim 1.

21. As to Claims 15-16, Mussi discloses a cell co-culture device (Fig. 1-4) which divides different cell groups and allows them to come into contact with each other (C4/L50-55); integrated cup-type culture container (12); tube having the cell culture diaphragm adhered to one end (14); and container which can hold the cup-type culture container and culture solution (Fig. 3).

22. Mussi does not appear to expressly disclose using the membrane of Tanaka in view of Meyering as shown in the rejection of Claim 6 above. However at the time of the invention it would have been obvious to a person having ordinary skill in the art to use the composite membrane of Tanaka in view of Meyering in the apparatus for cell co-culturing as it is well known that the honeycombed membrane structure is better for cultivating cells. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

23. Applicant's arguments filed November 16, 2010 have been fully considered but are not persuasive.

24. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

25. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Conclusion

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571)270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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